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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,518	09/14/2005	Stephen P. Massia	112624.00022	1335
26707	7590	11/15/2006	EXAMINER	
QUARLES & BRADY LLP RENAISSANCE ONE TWO NORTH CENTRAL AVENUE PHOENIX, AZ 85004-2391			LUKTON, DAVID	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 11/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/549,518

**Applicant(s)**

MASSIA ET AL.

**Examiner**

David Lukton

**Art Unit**

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-12 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Restriction to one of the following inventions is required under 35 U.S.C. §121:

- I. Claims 1, 2, 4-6, drawn to a composition that comprises N<sup>6</sup>-(Arginyl)-Lysine, or to a method of making a compound that contains N<sup>6</sup>-(Arginyl)-Lysine as a subunit.
- II. Claims 3 and 7-12, drawn to methods of using the composition of claim 6.

The claimed inventions are distinct.

The compound which applicants have referred to as "AAGPAHA" is really just N<sup>6</sup>-(Arginyl)-Lysine, i.e., the dipeptide Arg-Lys in which the arginine is bonded to the *epsilon* amino group of the lysine. This is a known compound; see, for example Szokan, Gy. (*Biopolymers* 42(3), 305-318, 1997) at page 314 column 1. In addition, the term "composition", as it is used in claim 1, could be interpreted to mean a "composition of matter". Use of the term "composition of matter" is improper where organic compounds are involved and where the structures are known; however, some applicants insist on using the term "composition of matter" anyway (to refer to organic compounds of known structure). As such, claim 1 could be interpreted to encompass any compound that comprises N<sup>6</sup>-(Arginyl)-Lysine; many such compounds are known. Thus, claim 1 does not "define a contribution" over the prior art. As for claim 2, this clearly encompasses a method of making any compound that contains the N<sup>6</sup>-(Arginyl)-Lysine dipeptide, since no final product is specified. It is probably true that there does not exist a valid rejection (of claim 2) under 35 USC §102. But it is likely the case that a

valid §103 rejection (of claim 2) could be cobbled together. Accordingly, Group I does not "define a contribution" over the prior art.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

In addition to the foregoing, applicants are required under 35 U.S.C. §121 to elect disclosed species (as follows) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

In the event that Group I is chosen for initial examination, election is required of each of the following

- a ) one of the following: (a) a specific compound, (b) a composition, (c) an implant, (d) a biomaterial, or (e) a method of synthesizing an RGD peptidomimetic;
- b ) in the event that "a specific compound" is chosen for initial examination (as indicated above in part (a)), identification of that compound is required;
- c ) in the event that a composition is chosen for initial examination, election of a fully defined composition is required.

. . . . .

In the event that Group II is chosen for initial examination, election is required of each of the following

- a ) the contents of the pharmaceutical composition of claim 6, wherein 100% of the ingredients are accounted for (i.e., the excipient should be specified);
- b ) a specific method (e.g., treatment of cancer).

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a generic claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentable distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103 of the other invention.



Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571)272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



DAVID LUKTON, PH.D.  
PRIMARY EXAMINER